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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,813	01/15/2004	Edgar B. Cahoon	BB1465USCNT	9069
23906 7590 05/04/2007 E I DU PONT DE NEMOURS AND COMPANY LEGAL PATENT RECORDS CENTER BARLEY MILL PLAZA 25/1128 4417 LANCASTER PIKE WILMINGTON, DE 19805			EXAMINER KAM, CHIH MIN	
			ART UNIT 1656	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/759,813	Applicant(s) CAHOON, EDGAR B.	
	Examiner Chih-Min Kam	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-24, 26, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-19, 23, 24, 26, 28 and 29 is/are rejected.
- 7) ☒ Claim(s) 20-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/1/06 (in part)</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 11-24, 26, 28 and 29 are pending.

Applicants' amendment filed December 26, 2006 is acknowledged. Applicant's response has been fully considered. Claims 11, 23 and 24 have been amended, and claims 25, 27 and 30 directed to non-elected invention have been cancelled. Therefore, claims 11-24, 26, 28 and 29 are examined.

The claim numbers of original claims 26, 28 and 29 have been changed to claims 25, 26 and 27, respectively by Applicants in the amendment, which is not proper because although claims 25, 27 and 30 have been cancelled, these cancelled claims should still maintain their claim numbers. Therefore, according to 37 CFR 1.126, the changed claims 25, 26 and 27 have been changed back to original claim numbers (i.e., claims 26, 28 and 29).

The status of claims 23 and 24 cited as "previously presented" is not correct because these claims have been amended in the amendment filed December 26, 2006.

Information Disclosure Statement

2. The references listed at pages 5-10 of Information Disclosure Statement filed June 1, 2004 have been considered (see attached signed 1449).

Withdrawn Informalities

3. The previous objection to the specification, regarding the title, the continuation data and recitation of "SEQ ID NO:", is withdrawn in view of applicants' amendment to the specification in the amendment filed December 26, 2006.

Withdrawn Claim Rejections - 35 USC § 101

4. The previous rejection of claims 23 and 24 under 35 U.S.C. 101 regarding the claimed invention being directed to non-statutory subject matter, is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 5-6 in the amendment filed December 26, 2006.

Withdrawn Claim Rejections - 35 USC § 112

5. The previous rejection of claim 20 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 7-8 in the amendment filed December 26, 2006.

6. The previous rejection of claims 11-24, 26, 28 and 29 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 6-7 in the amendment filed December 26, 2006.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 11-19, 23, 24, 26, 28 and 29 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 11-19, 23, 24, 26, 28 and 29 are directed to a polynucleotide comprising:

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a nucleotide sequence encoding a polypeptide which is a cytochrome P450 enzyme capable of producing delta12-epoxy fatty acids, wherein the polypeptide has at least 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85% or 90% identities to a polypeptide of SEQ ID NO:2, or the full complement of the nucleotide sequence (claims 11-19); a cell comprising the polynucleotide (claims 23-24); a vector or a recombinant construct comprising the polynucleotide (claims 28 and 29); or a method for transforming a cell by introducing into a cell the polynucleotide (claim 26). While the specification identifies the cDNA clone from *Euphorbia lagascae* (i.e., eellc.pk002.i4; Example 1) and the nucleotide sequence of SEQ ID NO:1 which encodes the amino acid sequence of a cytochrome P450 enzyme (i.e., SEQ ID NO:2) associated with the synthesis of the epoxy group of vernolic acid from *Euphorbia lagascae* (Table 1; Example 3); discloses expression of *Euphorbia lagascae* EST cell eellc.pk002.i4 in *Saccharomyces cerevisiae* (Example 7); and further indicates a polynucleotide encoding a polypeptide which is a cytochrome P450 enzyme associated with the synthesis of delta12-epoxy fatty acids, wherein the polypeptide has at least 50% identities to a polypeptide of SEQ ID NO:2, or the complement of the nucleotide sequence, wherein the complement and the nucleotide sequence contain the same number of nucleotides and are 100% complementary (page 2, lines 23-29; page 9, lines 9-24), the specification does not provide a genus of variants for polynucleotides encoding a polypeptide that is functional in the synthesis of epoxy group of fatty acids and has at least 50% identities to a polypeptide of SEQ ID NO:2, or the full complement of the nucleotide sequences. The description on the nucleotide sequence of SEQ ID NO:1 which encodes a functional SEQ ID NO:2, and on the alterations in nucleotide sequence that are not expected to alter functionality (page 7 line 4-page 8, line 11) does not provide a written description for the genus of variants of

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nucleic acid sequences which encode a functional enzyme that is at least 50% identity to SEQ ID NO:2. Furthermore, there is no description of any particular structure to function/activity relationship in the peptide variants encoded by the polynucleotides. Without guidance on the correlation of structure to function/activity of peptide variants, one skilled in the art would not know what nucleotide sequence would encode a functional polypeptide that is at least 50% identity to SEQ ID NO:2, and how to identify a functional protein from various nucleotide sequences. The lack of description of the correlation of structure to function/activity of peptide variants encoded by polynucleotides and the lack of representative species for the polynucleotide variants encoding a functional protein as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Response to Arguments

Applicants indicate the specification at page 7, line 4 through page 8 line 11, discloses alterations in nucleotide sequence that are not expected to alter functionality, such as alterations that produce a chemically equivalent amino acid at a given site or alterations in the N-or C-terminal portions. Thus, the skilled artisan would immediately understand the specification to disclose a representative number of polynucleotide sequences, having different nucleotide substitutions, that encode cytochrome P450 enzymes capable of producing epoxygenated delta-12 fatty acids but that vary (having at least 50% sequence identity) of SEQ ID NO:2. Furthermore, there is a correlation of structure and function with respect to the peptide variants encoded by the polynucleotides. For example, the distinctive features in the polypeptide sequence of cytochrome P450 enzymes described in Choe *et al.* The Plant Cell (1998) 10:231-

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243: (1) an I helix with the consensus sequence (A/G)GX(D/E)T(T/S), typical for group A cytochromes P450; and (2) a heme-binding domain with the consensus sequence PFG(AISN)GRRXC(PLAN)G. These same features can be found in the sequences of the instant invention (see attached Appendix A). Moreover, Examples 7, 8 and 9 disclose methods with respect to assessing the function of a P450 enzyme as an epoxy-group synthesizing enzyme. In view of the foregoing, withdrawal of the claims under 35 USC 35 USC 112, first paragraph, is respectfully requested (pages 6-7 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because of the following reasons. While the specification indicates alterations in nucleotide sequence such as alterations that produce a chemically equivalent amino acid at a given site or alterations in the N-or C-terminal portions that are not expected to alter functionality (page 7, line 4-page 8, line 11), it does not provide the sites of alteration in the nucleotide sequence, nor identify the resulting sequence encoding a functional enzyme, thus the specification does not disclose a representative number of polynucleotide sequences that encode cytochrome P450 enzymes capable of producing epoxygenated delta-12 fatty acids but that vary of SEQ ID NO:2. Furthermore, the two motifs of Choe *et al.* are found in the SEQ ID NO:2 (see Fig. 1; Appendix A), the specification does not indicate the claimed variants of SEQ ID NO:2 (having at least 50% sequence identity) are required to contain these two motifs, thus there is no correlation of structure and function with respect to the peptide variants encoded by the polynucleotides. Therefore, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

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Claim Objections

8. Claims 20-22 are objected to because the claims are dependent from a rejected claim.

Conclusions

9. Claims 11-19, 23, 24, 26, 28 and 29 are rejected; and claims 20-22 are objected to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

April 26, 2007